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EXAMINER	
POUS, NATALIE R	
ART UNIT	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,209	NITA ET AL.	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Regarding Amended Independent Claim 1

1. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection based on applicants amendment.

Regarding Amended Independent Claim 8

2. Applicant's arguments with respect to claim 8 have been considered but are moot in view of the new ground(s) of rejection based on applicants amendment.

Regarding Amended Independent Claim 12

3. Applicant's arguments with respect to claim 12 have been considered but are moot in view of the new ground(s) of rejection based on applicants amendment.

Regarding Independent Claim 16

4. Applicant's arguments, see page 13, filed 1/6/07, with respect to the rejection(s) of claim(s) 16 under 35 USC 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made, see below.

Regarding Amended Independent Claim 20

5. Applicant's arguments with respect to claim 20 have been considered but are moot in view of the new ground(s) of rejection based on applicants amendment.

Regarding Amended Independent Claim 32

6. Applicant's arguments with respect to claim 32 have been considered but are moot in view of the new ground(s) of rejection based on applicants amendment.

Regarding the first rejection under 35 USC 103

7. Applicant's arguments with respect to claims 2, 3 and 9 have been considered but are moot in view of the new ground(s) of rejection based on applicants amendment.

Regarding the second rejection under 35 USC 103

8. Applicant's arguments with respect to claims 6 and 10 have been considered but are moot in view of the new ground(s) of rejection based on applicants amendment.

Regarding the third rejection under 35 USC 103

9. Applicant's arguments, see page 16, filed 1/6/07, with respect to the rejection(s) of claim(s) 26 under 35 USC 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made, see below.

Applicant's arguments with respect to claims 29-31 have been considered but are moot in view of the new ground(s) of rejection.

Regarding the fourth rejection under 35 USC 103

10. Applicant asserted that it appeared the intent was for claims 5 and 7 to be rejected in view of Brennan and Bencini as opposed to Brennan and Ferrera, and applicant is correct in this assumption. Further, applicant's arguments with respect to claims 5 and 7 have been considered but are moot in view of the new ground(s) of rejection based on applicants amendment.

Regarding the 112 Rejections

11. applicants amendments overcome the previous 35 USC 112 rejections. These rejections are thus withdrawn.

Regarding the fifth rejection under 35 USC 103

12. Applicant's arguments with respect to claim 20 have been considered but are not persuasive. Applicant argues that it has not been shown that Passafaro or Brennan teach an ultrasound transmission member that contacts the guidewire. Examiner respectfully disagrees. As seen in figure 5 of Passafaro, an opening (92) in guidewire tube (90) is present to allow passage of ultrasound transmission member (28). It is inevitable that given the size of the device and the means by which it will be used (i.e. maneuvered through tortuous vasculature) that the transmission member (passing though the opening of the guidewire tube) and the guidewire will contact each other. Thus examiner sustains the previous 35 USC 103 rejection of claims 20 and 23-25 with respect to Passafaro and Brennan.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 1, 4 and 12-15, are rejected under 35 U.S.C. 103(a) as being unpatentable over Nita et al. (US 5368557) in view of Brennan et al. (US 6450975). Nita teaches an ultrasound catheter for disrupting occlusions in blood vessels which can be guided from an access site on a patients body on a patient's body to a target site adjacent an occlusion, the ultrasound catheter comprising:

An elongate flexible catheter body (11) having a proximal portion, a distal portion, and at least one lumen, an ultrasound transmission member (84) extending longitudinally through the lumen of the catheter body and having a proximal end (84) and a distal end (28a-28c), wherein the ultrasound transmission member is more flexible near its distal end than near its proximal end (it is noted that the portion of the transmission wire split into multiple segments near the distal end will inherently be more flexible than a single, thicker transmission member); a distal head (30) coupled with the distal end of the ultrasound transmission member and disposed adjacent the distal en of the catheter body (fig. 3); a guidewire tube (50) that contacts the ultrasound member (it is noted that it is inevitable that given the size of the device and the means by which it will be used (i.e. maneuvered through tortuous vasculature) that the transmission member and the guidewire tube (50) will contact each other); and at least one coupling member (14) for coupling the ultrasound transmission member with a source of ultrasound energy, and wherein the guidewire tube (50) has a distal end that is flush with the distal end of the distal head (30, fig. 3)

Nita fails to teach wherein the proximal portion of the catheter body is stiffer than the distal portion, and the distal portion is more flexible near the distal end of the

catheter body than near the proximal portion of the catheter body, wherein cross-sectional diameter of the catheter body is less along the distal portion than along the proximal portion, and wherein a cross-sectional diameter of the ultrasound transmission wire is less near the distal end than near the proximal end, wherein the distal portion of the catheter body and the ultrasound transmission wire are sufficiently flexible to conform concomitantly to multiple bends in the guidewire wherein the distal portion of the catheter body and the ultrasound transmission member are sufficiently flexible to conform concomitantly to multiple bends in a blood vessel guidewire and wherein the distal portion of the catheter body, the ultrasound transmission wire and the guidewire may be passed together or sequentially through the multiple bends in the blood vessel while conforming concomitantly to the multiple bends.

Brennan teaches an ultrasound catheter body wherein proximal portion of the catheter body is stiffer than the distal portion, and the distal portion is more flexible near the distal end of the catheter body than near the proximal portion of the catheter body and wherein cross-sectional diameter of the catheter body is less along the distal portion than along the proximal portion, and wherein a cross-sectional diameter of the ultrasound transmission wire is less near the distal end than near the proximal end (fig. 5), wherein the distal portion of the catheter body and the ultrasound transmission wire are sufficiently flexible to conform concomitantly to multiple bends in the guidewire (Column 7, proximate lines 58-67), wherein the distal portion of the catheter body and the ultrasound transmission member are sufficiently flexible to conform concomitantly to multiple bends in a blood vessel guidewire (Column 7, proximate lines 58-67) and

wherein the distal portion of the catheter body, the ultrasound transmission wire and the guidewire may be passed together or sequentially through the multiple bends in the blood vessel while conforming concomitantly to the multiple bends (Column 10, proximte lines 8-34), such that the catheter body can more easily maneuver through the vasculature. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Nita as taught by Brennan so that the catheter body can more easily maneuver through the vasculature.

14. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Nita and Brennan as applied to claim 1 above, and further in view of Bencini et al. (US 6544215). The combination of Nita and Brennan teaches all limitations of preceding dependent claim 1 as previously described, but fails to teach the following:

- wherein the distal portion is sufficiently flexible to pass, without kinking, through at least 5 cm of a blood vessel having at least one bend and an inner diameter of between about 2 mm and about 5 mm
- wherein the at least one bend has a radius of about 1.0 cm or smaller
- a distal portion having at least one bend

Bencini et al teach a steer able catheter wherein the distal portion has a bend and is sufficiently flexible to pass, without kinking, through at least 5 cm of a blood vessel having at least one bend and an inner diameter of between about 2 mm and about 5 mm wherein the at least one bend has a radius of about 1.0 cm or smaller (column 5, proximate lines 55-67) in order to bend through tortuous blood vessels, and yet have

sufficient memory to return to its original orientation when bending forces are removed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Nita and Brennan with the dimensions as disclosed by Bencini in order to bend through tortuous blood vessels, and yet have sufficient memory to return to its original orientation when bending forces are removed.

15. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Nita and Brennan, and further in view of Ferrera et al. (US 6616617). The combination of Nita and Brennan teaches all limitations of preceding dependent claims 1 and 4 as previously described but fails to teach wherein a wall thickness of the catheter body is less along the distal portion than along the proximal portion. Ferrera teaches a catheter for vascular navigation wherein the wall thickness of the catheter may vary to provide desired variations in bending or stiffness of the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Nita and Brennan with a catheter of varied thickness in order to further enhance the stiffness of the proximal end and the flexibility of the distal end.

16. Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Nita, Brennan and Bencini and further as a matter of design choice. The combination of Nita, Brennan and Bencini teaches all limitations of preceding dependent claims 1, 4, 6 as previously described, but does not teach:

- wherein the cross-sectional diameter of the catheter body is between about 0.102 cm and about 0.178 cm along its proximal end and between about 0.076 cm and about 0.127 cm along its distal end
- the cross-sectional diameter of the ultrasound transmission member is between about 0.051 cm and about 0.102 cm near its proximal end and between about 0.013 cm and about 0.038 cm near its distal end.
- wherein the wall thickness is between about 0.007 cm to about 0.020 cm along its proximal portion and about 0.005 cm to about 0.013 cm along its distal portion.
- wherein the wall thickness is between about 0.007 cm to about 0.020 cm along its proximal portion and about 0.005 cm to about 0.013 cm along its distal portion.

The combination of Nita, Brennan and Bencini does teach a catheter system for navigating through bends in the vascular system, and it appears that the combination of Nita, Brennan and Bencini performs the task of navigating through bends in the vascular system by providing a more rigid proximal section and a more flexible distal section equally well as that of the application. It would therefore have been an obvious matter of design choice to provide the dimensions as disclosed in the application since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

17. Claim 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nita in view of Brennan and further in view of Khairkhahan et al. (US 6179809).

Nita teaches an ultrasound catheter for disrupting occlusions in blood vessels which can be guided from an access site on a patients body on a patient's body to a target site adjacent an occlusion, the ultrasound catheter comprising:
An elongate flexible catheter body (11) having a proximal portion, a distal portion, and at least one lumen, an ultrasound transmission member (84) extending longitudinally through the lumen of the catheter body and having a proximal end (84) and a distal end (28a-28c), wherein the ultrasound transmission member is more flexible near its distal end than near its proximal end (it is noted that the portion of the transmission wire split into multiple segments near the distal end will inherently be more flexible than a single, thicker transmission member); a distal head (30) coupled with the distal end of the ultrasound transmission member and disposed adjacent the distal end of the catheter body (fig. 3); and at least one coupling member (14) for coupling the ultrasound transmission member with a source of ultrasound energy.

Nita fails to teach wherein the proximal portion of the catheter body is stiffer than the distal portion, and the distal portion is more flexible near the distal end of the catheter body than near the proximal portion of the catheter body, wherein the distal portion of the catheter body and the ultrasound transmission wire are sufficiently flexible to conform concomitantly to multiple bends in the guidewire wherein the distal portion of the catheter body and the ultrasound transmission member are sufficiently flexible to conform concomitantly to multiple bends in a blood vessel guidewire and wherein the

distal portion of the catheter body, the ultrasound transmission wire and the guidewire may be passed together or sequentially through the multiple bends in the blood vessel while conforming concomitantly to the multiple bends.

Brennan teaches an ultrasound catheter body wherein proximal portion of the catheter body is stiffer than the distal portion, and the distal portion is more flexible near the distal end of the catheter body than near the proximal portion of the catheter body and wherein cross-sectional diameter of the catheter body is less along the distal portion than along the proximal portion, and wherein a cross-sectional diameter of the ultrasound transmission wire is less near the distal end than near the proximal end (fig. 5), wherein the distal portion of the catheter body and the ultrasound transmission wire are sufficiently flexible to conform concomitantly to multiple bends in the guidewire (Column 7, proximate lines 58-67), wherein the distal portion of the catheter body and the ultrasound transmission member are sufficiently flexible to conform concomitantly to multiple bends in a blood vessel guidewire (Column 7, proximate lines 58-67) and wherein the distal portion of the catheter body, the ultrasound transmission wire and the guidewire may be passed together or sequentially through the multiple bends in the blood vessel while conforming concomitantly to the multiple bends (Column 10, proximte lines 8-34), such that the catheter body can more easily maneuver through the vasculature. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Nita as taught by Brennan so that the catheter body can more easily maneuver through the vasculature.

The combination of Nita and Brennan fails to teach wherein the distal portion of the catheter body comprises at least one bend. Khairkhahan teaches a catheter with a guidewire, wherein the catheter comprises at least one bend, to which the guidewire confirms, in order to aid in maneuvering the catheter to the desired location in the vasculature. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Nita and Brennan as taught by Khairkhahan in order to aid in maneuvering the catheter to the desired location in the vasculature.

18. Claims 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Passafaro et al. (US 5324255) in view of Brennan.

Passafaro teaches an ultrasound catheter for disrupting occlusions in blood vessels which can be guided from an access site on a patients body on a patient's body to a target site adjacent an occlusion, the ultrasound catheter comprising:
An elongate flexible catheter body having a proximal portion, a distal portion, at least one lumen, and a guidewire tube (90) disposed within the lumen; an ultrasound transmission member (28) extending longitudinally through the lumen of the catheter body; a distal head (104) coupled with the distal end of the ultrasound transmission member and disposed adjacent the distal end of the catheter body (fig. 4); and at least one coupling member (22) for coupling the ultrasound transmission member with a source of ultrasound energy; wherein the guidewire tube (90) includes at least one opening (92) within the catheter body for providing contact between the a guidewire extending through the guidewire tube and the ultrasound transmission member, and

wherein the ultrasound transmission member (28) passes through the guidewire tube (90) via the at least one opening (92) to contact the guidewire (fig. 5)

Passafaro fails to teach wherein the proximal portion of the catheter is stiffer than the distal portion, wherein the distal portion of the catheter body is more flexible near a distal end of the catheter body than near the proximal portion of the catheter body and wherein the ultrasound transmission member comprises a proximal end and a distal end, and wherein the ultrasound transmission member is more flexible near its distal end than near its proximal end.

Brennan teaches an ultrasound catheter body wherein proximal portion of the catheter body is stiffer than the distal portion, and the distal portion is more flexible near the distal end of the catheter body than near the proximal portion of the catheter body, wherein the distal portion of the catheter body is more flexible near a distal end of the catheter body than near the proximal portion of the catheter body (Column 8, proximate lines 19-27) and wherein the ultrasound transmission member comprises a proximal end and a distal end, and wherein the ultrasound transmission member is more flexible near its distal end than near its proximal end (Column 8, proximate lines 19-27), such that the catheter body can more easily maneuver through the vasculature. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Nita as taught by Brennan so that the catheter body can more easily maneuver through the vasculature.

The combination of Passafaro and Brennan fail to teach wherein the guidewire contacts the ultrasound transmission wire nearer to the distal end and nearer to the

center of the catheter body. It would have been an obvious matter of design choice to position the aperture (92, Passafaro) nearer to the center or distal end of the device since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

19. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nita et al. (US 5312328) in view of Brennan et al. (US 6450975).

Nita teaches an ultrasound catheter for disrupting occlusions in blood vessels which can be guided from an access site on a patients body on a patient's body to a target site adjacent an occlusion, the ultrasound catheter comprising:
An elongate flexible catheter body (10) having a proximal portion, a distal portion, and at least one lumen; an ultrasound transmission member (24) extending longitudinally through the lumen of the catheter body and having a proximal end and a distal end (24d), wherein the ultrasound transmission member is more flexible near its distal end than near its proximal end (it is noted that the portion of the transmission wire (24d) that is thinner than the thicker proximal portion (24p) will inherently be more flexible); a distal head (26b) coupled with the distal end of the ultrasound transmission member and disposed adjacent the distal en of the catheter body (fig. 3); a guidewire tube (156) that extends partially through the distal head, the guidewire tube having a distal end that is proximal to a distal end of the distal end of the distal head (fig. 6b); and at least one coupling member (92) for coupling the ultrasound transmission member with a source of ultrasound energy, the at least one coupling member comprising a housing fixedly

coupled with the proximal end of the catheter body, such that torque applied to the housing is transmitted along the catheter body to its distal portion (fig. 8)

Nita fails to teach wherein the proximal portion of the catheter body is stiffer than the distal portion, and the distal portion is more flexible near the distal end of the catheter body than near the proximal portion of the catheter body. Brennan teaches an ultrasound catheter body wherein proximal portion of the catheter body is stiffer than the distal portion, and the distal portion is more flexible near the distal end of the catheter body than near the proximal portion of the catheter body, such that the catheter body can more easily maneuver through the vasculature. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Nita as taught by Brennan so that the catheter body can more easily maneuver through the vasculature.

20. Claims 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nita et al. (US 5368557) in view of Brennan et al. (US 6450975) and further as a matter of design choice.

Nita teaches an ultrasound catheter for disrupting occlusions in blood vessels which can be guided from an access site on a patients body on a patient's body to a target site adjacent an occlusion, the ultrasound catheter comprising:

An elongate flexible catheter body (11) having a proximal portion, a distal portion, and at least one lumen, an ultrasound transmission member (84) extending longitudinally through the lumen of the catheter body and having a proximal end (84) and a distal end (28a-28c); a distal head (30) coupled with the distal end of the

ultrasound transmission member and disposed adjacent the distal end of the catheter body (fig. 3), the distal head including: a guidewire aperture (54) in a center of a distal end of the distal head; a guidewire lumen extending through the distal head; and at least one coupling member (14) for coupling the ultrasound transmission member with a source of ultrasound energy

Wherein the guidewire lumen includes a cavity in which a distal end of a guidewire tube (50) of the catheter body is disposed (fig. 3)

Wherein the cavity extends through the distal end of the distal head, such that the distal end of the guidewire tube is flush with the distal end of the head (fig. 3)

Nita fails to teach wherein the proximal portion of the catheter body is stiffer than the distal portion, and the distal portion is more flexible near the distal end of the catheter body than near the proximal portion of the catheter body, wherein cross-sectional diameter of the catheter body is less along the distal portion than along the proximal portion, and wherein a cross-sectional diameter of the ultrasound transmission wire is less near the distal end than near the proximal end, wherein the distal portion of the catheter body and the ultrasound transmission wire are sufficiently flexible to conform concomitantly to multiple bends in the guidewire wherein the distal portion of the catheter body and the ultrasound transmission member are sufficiently flexible to conform concomitantly to multiple bends in a blood vessel guidewire and wherein the distal portion of the catheter body, the ultrasound transmission wire and the guidewire may be passed together or sequentially through the multiple bends in the blood vessel while conforming concomitantly to the multiple bends.

Brennan teaches an ultrasound catheter body wherein proximal portion of the catheter body is stiffer than the distal portion, and the distal portion is more flexible near the distal end of the catheter body than near the proximal portion of the catheter body and wherein cross-sectional diameter of the catheter body is less along the distal portion than along the proximal portion, and wherein a cross-sectional diameter of the ultrasound transmission wire is less near the distal end than near the proximal end (fig. 5), wherein the distal portion of the catheter body and the ultrasound transmission wire are sufficiently flexible to conform concomitantly to multiple bends in the guidewire (Column 7, proximate lines 58-67), wherein the distal portion of the catheter body and the ultrasound transmission member are sufficiently flexible to conform concomitantly to multiple bends in a blood vessel guidewire (Column 7, proximate lines 58-67) and wherein the distal portion of the catheter body, the ultrasound transmission wire and the guidewire may be passed together or sequentially through the multiple bends in the blood vessel while conforming concomitantly to the multiple bends (Column 10, proximte lines 8-34), such that the catheter body can more easily maneuver through the vasculature. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Nita as taught by Brennan so that the catheter body can more easily maneuver through the vasculature.

The combination of Nita and Brennan fails to teach wherein the guidewire lumen has a different, non-parallel longitudinal axis than a longitudinal axis of the catheter body. Due to lack of criticality in the specification, the non-parallel portion of the guidewire lumen was shown to solve no particular problem, serve no particular purpose

and provide no additional benefit as opposed to lumen parallel to the longitudinal axis of the catheter. Therefore, it would have been obvious to make the guidewire lumen non-parallel because it is capable of facilitating tracking of the catheter device along guidewire equally as well as the present application.

21. Claims 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Nita and Brennan as a matter of design choice as applied to claim 8 above, and further in view of Bencini et al. (US 6544215). The combination of Nita and Brennan teaches all limitations of preceding dependent claim 8 as previously described, but fails to teach the following:

- wherein the distal portion is sufficiently flexible to pass, without kinking, through at least 5 cm of a blood vessel having at least one bend and an inner diameter of between about 2 mm and about 5 mm

Bencini et al teach a steerable catheter wherein the distal portion has a bend and is sufficiently flexible to pass, without kinking, through at least 5 cm of a blood vessel having at least one bend and an inner diameter of between about 2 mm and about 5 mm wherein the at least one bend has a radius of about 1.0 cm or smaller (column 5, proximate lines 55-67) in order to bend through tortuous blood vessels, and yet have sufficient memory to return to its original orientation when bending forces are removed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Nita and Brennan with the dimensions as disclosed by Bencini in order to bend through tortuous blood vessels, and yet have sufficient memory to return to its original orientation when bending forces are removed.

22. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Nita and Brennan as a matter of design choice, and further in view of Ferrera et al. (US 6616617) as a matter of design choice.

The combination of Nita and Brennan teaches all limitations of preceding dependent claim 8 as previously described but fails to teach wherein a wall thickness of the catheter body is less along the distal portion than along the proximal portion. Bencini teaches a catheter for vascular navigation wherein the wall thickness of the catheter may vary to provide desired variations in bending or stiffness of the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Nita and Brennan with a catheter of varied thickness in order to further enhance the stiffness of the proximal end and the flexibility of the distal end.

The combination of Nita, Brennan and Ferrera does teach a catheter system for navigating through bends in the vascular system, and it appears that the combination of Nita, Brennan and Ferrera performs the task of navigating through bends in the vascular system by providing a more rigid proximal section and a more flexible distal section equally well as that of the application. It would therefore have been an obvious matter of design choice to provide the dimensions as disclosed in the application since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

23. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Nita, and Brennan as a matter of design choice and further in view of Nita et al. (US 5312328), hereinafter, Nita '328. The combination of Nita, Brennan as a matter of design choice teaches all limitations of preceding dependent claims 26 and 29, but fails to teach wherein the cavity extends partially through the distal head, such that the distal end of the guidewire tube is disposed proximal to the distal end of the distal head. Nita '328 teaches wherein the cavity extends partially through the distal head, such that the distal end of the guidewire tube is disposed proximal to the distal end of the distal head (fig. 6b). Due to lack of criticality in the specification, partially extending guidewire tube was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to the guidewire tube extending through and being flush with the distal end of the distal head. Therefore, it would have been obvious to make the guidewire lumen partially extended, since it is capable of facilitating tracking of the catheter device along guidewire equally as well as that of the present application.

Conclusion

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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